



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                | CONFIRMATION NO.       |
|--|-------------|----------------------|------------------------------------|------------------------|
| 10/626,931   | 07/25/2003  | Dean A. Klein        | 54459-277675                       | 5405                   |
| 25764 7590 10/31/2007<br>FAEGRE & BENSON LLP<br>PATENT DOCKETING<br>2200 WELLS FARGO CENTER<br>90 SOUTH SEVENTH STREET<br>MINNEAPOLIS, MN 55402-3901 |             |                      | EXAMINER<br>MEHTA, PARIKHA SOLANKI |                        |
|  |             |                      | ART UNIT<br>3737                   | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>10/31/2007            | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/626,931

Applicant(s)

KLEIN ET AL.

Examiner

Parikha S. Mehta

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 3737

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1-83 have been considered but are moot in view of the new ground(s) of rejection.

### ***Information Disclosure Statement***

2. In the remarks filed 13 August 2007, Applicant indicated filing of a supplemental Information Disclosure Statement (Remarks p.1). However, no such statement was included in the submission. Accordingly, Examiner was unable to consider the references to which Applicant refers.

### ***Drawings***

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the marker of claims 1-83 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

4. Claim 79 is objected to because of the following informalities: the word "sight" incorrectly appears where the word "site" should be used. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless—

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-32, 35, 39-67, and 70-83 are rejected under 35 U.S.C. 102(b) as being anticipated by Klein (US Patent No. 6,394,965), hereinafter Klein ('965), previously made of record.

**Regarding claims 1-3, 5-15, 17-26, 42-48 and 67**, Klein ('965) discloses a method of implanting a plurality of marker microparticles comprising carbon-coated zirconium oxide in a breast lesion, forming an image of the lesion, and treating the lesion with radiation therapy based on the information shown in the image (co. 2 lines 10-40, col. 3 lines 51-65). As disclosed by Applicant (Specification p. 19), carbon-coated zirconium oxide, as disclosed by Klein ('965), is detectable in x-ray, mammography and MRI. The biopsy and progress monitoring of Klein ('965) (col. 3 lines 58-62, col. 10 lines 6-27) constitute computer assisted diagnosis and forming multiple images as claimed in the instant application.

**Regarding claim 16**, Klein ('965) discloses performing surgery based on the mammographic findings (col. 10 lines 28-34).

**Regarding claims 49-61, 63 and 80-83**, Klein ('965) discloses a detectable marker for implantation at an anatomical site comprising a carbon-coated zirconium oxide or aluminum oxide substrate, for a wide variety of imaging modalities including magnetic resonance imaging, fluoroscopy and x-ray (col. 2 lines 10-40, col. 3 lines 35-41).

**Regarding claim 62**, Klein ('965) discloses that the carbon coating may comprise pyrolytic carbon, vitreous carbon or graphite (col. 2 lines 24-30).

**Regarding claims 64-66**, Klein ('965) discloses the marker to be of a major dimension between 100-1000  $\mu\text{m}$ , which constitutes a dimension of between about 80-10,000  $\mu\text{m}$ , 800-3,500  $\mu\text{m}$ , and 1,000 and 3,000  $\mu\text{m}$  as claimed.

Art Unit: 3737

**Regarding claims 27, 28, 70-73,** Klein ('965) discloses that the marker may comprise gold or titanium (col. 3 lines 25-33).

**Regarding claims 29-32 and 74-78,** Klein ('965) discloses that the marker may comprise a biocompatible gel carrier, including  $\beta$ -glucan (col. 2 lines 41-50, col. 8 lines 26-44).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 35 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('965). Klein ('965) substantially teaches all features of the present inventive method as previously discussed for claim 42, but does not expressly discuss steps for radiation therapy. Examiner hereby takes Official Notice that it is well known in the art to mark cancerous lesions for subsequent location of the lesion by imaging in radiation therapy, which necessarily requires pre-positioning of the body prior to imaging as claimed in the instant application. Accordingly, one of ordinary skill in the art at the time of invention would have found it obvious to perform the marking method of Klein ('965) in accordance with the state of the art lesion locating techniques for radiation therapy in order to achieve the claimed invention.

Regarding claims 68 and 69, Applicant does not provide sufficient evidence that including a hollow, liquid-filled portion in the marker solves a particular problem or presents a patentable advantage over the prior art. Accordingly it would have been an obvious matter of design choice to one of ordinary skill in the art at the time of invention to change the marker of Klein ('965) such that the biocompatible gel is disposed in a recess within the particle to achieve the claimed invention (see MPEP § 2144).

9. Claims 33, 34 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('965) in view of McCrory (US PG Pubs. No. 2001/0004395 A1), hereinafter McCrory ('395), previously made of record.

**Regarding claims 33, 34 and 36-38,** Klein ('965) substantially teaches all features of the present invention as previously discussed, with the exception of explicit steps for forming a second image and synthesizing the two images to obtain positional information. In the same field of endeavor, McCrory

Art Unit: 3737

('395) teaches of multimodal image registration for locating a lesion over multiple radiation sessions. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Klein ('965) to perform the additional imaging step and image registration as taught by McCrory ('395), as the combination of prior art elements according to known methods to yield predictable results is not considered a patentable advance in the art (see for precedence see for precedent *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

### *Conclusion*

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha S. Mehta whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

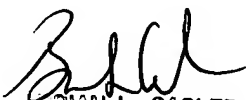
Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Parikha S. Mehta

Examiner – Art Unit 3737

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3737